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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,685	07/03/2003	Yehoshua Shachar	EMAG.001A	7408

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,685	SHACHAR, YEHOSHUA	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39 and 41-64* is/are pending in the application.

4a) Of the above claim(s) *6-32,34-39 and 41-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 12/27/2006.

2. In the reply, the Applicant amended claims 1-5, 33 and cancelled claim 40. Claims 6-32, 34-39, 41-64 remain withdrawn.

3. The Applicant amended the Specification and Title of the invention to obviate the objection to the specification.

4. Additionally, the Applicant filed formal drawings obviating the objection to the drawings.

5. Thus, claims 1-5, 33 are pending for examination.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "synegeneic". The Applicant fails to provide antecedent basis for this limitation in the drawings or claims. A synegeneic material denotes a material or tissue that has an identical geneotype, ie is identically identical, to the tissue it is implanted into. The specification fails to provide antecedent

basis for this claim. Rather, the implantable biodegradable skin is described as biocompatible.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-5, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty (6749587).

10. Flaherty discloses an implantable apparatus comprising: an implantable (Fig 2, col 13, lns 12-43) pouch (10) having one or more chambers composed of a bioabsorbable material (30; col 22, lns 18-24); at least one medicating agent (col 3, lns 33-44) disposed in said one or more chambers; and at least one implantable piezoelectric pump (46, col 7, lns 32-33; col 15, lns 20-23) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient (Summary); and an implantable, biocompatible and biodegradable skin (702, 802; col 9, lns 10-col 10, lns 8; col 22, lns 18-24) covering the pouch and pump; further comprising an implanted control circuit (50) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said

medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously with local homeostatic parameters (col 11, lns 13-col 12, lns 3; col 13, lns 12-42); a control circuit (50) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted sensor (col 11, lns 13-col 12, lns 3; col 13, lns 12-42) to measure a local homeostatic response related to the medicating agent, where the control circuit controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor (col 11, lns 13-col 12, lns 3; col 13, lns 12-42); further comprising a control circuit (50) to control said at least one piezoelectric pump to provide for autonomously regulating, controlling, and modulating a combination therapy of cytokine and chemotherapeutic agents for the purpose of tumor elimination in a closed loop control mode (col 11, lns 13-col 12, lns 3; col 13, lns 12-42); further comprising an implantable wireless bi-directional communications link (Fig 1; 60; 100; col 6, lns 12-24) coupled to the implanted sensor through the implanted control circuit.

11. Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al (6541021).

12. Johnson et al discloses an implantable apparatus comprising: an implantable pouch (Figs 1-4) having one or more chambers composed of a bioabsorbable material (col 10, lns 37-43); at least one medicating agent (Summary) disposed in said one or more chambers; and at least one implantable piezoelectric pump (col 7, lns 44; col 17,

lns 53-67) fabricated in the pouch which forms a skeleton of the pump (Figs 2, 4), the pump being configured to transfer said at least one medicating agent to said patient (Summary); and an implantable, biocompatible and biodegradable skin (col 10, lns 37-43) covering the pouch and pump.

13. Claims 1-4, 33 rejected under 35 U.S.C. 102(e) as being anticipated by Humes et al (2002/0090388).

14. Humes et al discloses an implantable apparatus comprising: an implantable pouch ([0002]) having one or more chambers composed of a bioabsorbable material ([0003]); at least one medicating agent ([0011]) disposed in said one or more chambers; and at least one implantable piezoelectric pump ([0018, 0094, 0098]) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient ([0018, 0078, 0094]); and an implantable, biocompatible and biodegradable skin ([0003, 0103-0109]) covering the pouch and pump; further comprising an implanted control circuit ([0094-0095]) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously with local homeostatic parameters ([0094-0095]); a control circuit ([0094-0095]) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted sensor ([0094-0095]) to measure a local homeostatic response related to the medicating agent, where the control circuit

controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor ([0094-0095); further comprising an implantable wireless bi-directional communications link ([0094]) coupled to the implanted sensor through the implanted control circuit.

15. Claims 1-3, 33 rejected under 35 U.S.C. 102(b) as being anticipated by Soykan et al (6206914).

16. Soykan et al discloses an implantable apparatus comprising: an implantable pouch (Fig 1, 2, 5; Summary) having one or more chambers composed of a bioabsorbable material (col 9, lns 61-col 10, lns 3, 47-63); at least one medicating agent (Summary, col 13, lns 16-27) disposed in said one or more chambers; and at least one implantable piezoelectric pump (col 13, lns 16-27) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient (col 13, lns 16-27); and an implantable, biocompatible and biodegradable skin (Figs 1, 2, Summary; col 9, lns 61-col 10, lns 3, 47-63) covering the pouch and pump; further comprising an implanted control circuit (Fig 5) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously with local homeostatic parameters (Summary, col 15, lns 13-col 16, lns 11); a control circuit (Fig 5) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted

sensor (col 16, lns 24-61) to measure a local homeostatic response related to the medicating agent, where the control circuit controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor (col 15, lns 13-col 16, lns 61); further comprising an implantable wireless bi-directional communications link (col 15, lns 13-58) coupled to the implanted sensor through the implanted control circuit.

Response to Arguments

17. Applicant's arguments with respect to claims 1-5, 33, and 40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER